AMENDMENTS TO THE CLAIMS

Applicants respectfully request that this Listing of Claims replace all prior versions and listings of claims in this application:

Listing of Claims

1.-177. (canceled)

178. (New) A solid oral dosage form which is effective in delivering a drug and an enhancer, each as defined below, to an intestine and which comprises a pharmaceutical composition consisting essentially of:

(A) about 0.5 μg to about 1000 mg of a drug which: (1) is present in a therapeutically effective amount; (ii) is crystalline or amorphous; and (iii) is hydrophilic or macromolecular; and

(B) an enhancer which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon chain length of from 8 to 14 carbon atoms and is the only enhancer present in the composition; (iii) is present in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:100,000 to 10:1 and such that the enhancer enhances intestinal delivery of the drug to the underlying circulation.

179. (New) A form according to claim 178 wherein the composition has thereon an enteric coating.

180. (New) A form according to claim 179 wherein the enteric-coated composition is a tablet.

181. (New) A form according to claim 178 including a capsule which contains said composition and which has thereon an enteric coating.

182. (New) A form according to claim 180 wherein the composition includes:

(A) a drug selected from the group consisting of peptides, proteins, oligosaccharides polysaccharides, and hormones; and

(B) an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

183. (New) A form according to claim 180 which includes an anticoagulant drug and an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

184. (New) A form according to claim 183 wherein the anticoagulant drug is selected from the group consisting of heparin, low molecular weight heparins, heparanoids, hirudin, and analogues of the foregoing.

185. (New) A form according to claim 184 including heparin.

186. (New) A form according to claim 184 including low molecular weight heparin.

187. (New) A form according to claim 185 wherein the enhancer is sodium caprate and the ratio of the heparin to the sodium caprate is 1:1000 to 10:1.

188. (New) A form according to claim 186 wherein the enhancer is sodium caprate and the ratio of the low molecular heparin to the sodium caprate is 1:1000 to 10:1.

189. (New) A form according to claim 180 wherein the composition includes a bisphosphonate.

190. (New) A form according to claim 189 wherein the bisphosphonate is alendronate.

191. (New) A form according to claim 189 wherein the bisphosphonate is etidronate.

192. (New) A form according to claim 190 wherein the enhancer is sodium caprate and the ratio of the alendronate to the sodium caprate is 1:1000 to 10:1.

193. (New) A form according to claim 182 wherein the composition includes a peptide drug.

194. (New) A form according to claim 182 wherein the composition includes a protein drug.

195. (New) A form according to claim 182 wherein the composition includes an oligosaccharide drug.

196. (New) A form according to claim 182 wherein the composition includes a polysaccharide drug.

197. (New) A form according to claim 182 wherein the composition includes a hormone drug.

198. (New) A form according to claim 178 wherein the enhancer is sodium caprate.

199. (New) A form according to claim 180 wherein the enhancer is sodium caprate.

200. (New) A form according to claim 180 wherein the tablet is a sustained-release tablet.

201. (New) A form according to claim 200 wherein the composition includes a rate-controlling polymeric material.

202. (New) A form according to claim 201 wherein the polymeric material is hydroxypropyl-methylcellulose.

203. (New) A form according to claim 180 wherein the enteric-coated tablet is an instant-release tablet.

204. (New) A form according to claim 180 wherein the enteric coating comprises a polymer selected from the group consisting of poly(acrylic acid), polyacrylate, poly(methacrylic acid) and polymethacrylate, and mixtures thereof.

205. (New) A form according to claim 178 wherein the composition is in the form of a multiparticulate.

206. (New) A form according to claim 205 wherein the multiparticulate is in the form of a tablet.

207. (New) A form according to claim 199 wherein the drug is a bisphosphonate.

208. (New) A form according to claim 199 wherein the drug is heparin.

209. (New) A form according to claim 199 wherein the drug is a low molecular weight heparin.

210. (New) A form according to claim 178 wherein the enhancer is a combination of medium chain fatty acid salts having a carbon chain length of from 8 to 14 carbon atoms and the combination is the only enhancer present in the composition.

211. (New) A compressible composition which is capable of being compressed into a solid oral pharmaceutical dosage form which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to an intestine, said composition consisting essentially of:

(A) a drug which is: (i) crystalline or amorphous; and (ii) hydrophilic or macromolecular; and

(B) an enhancer which is: (i) a solid at room temperature; (ii) a salt of a medium chain fatty acid having a carbon chain length of from 8 to 14 carbon atoms and is the only enhancer present in the composition; and (iii) present in an amount and such that the ratio of the drug to the enhancer is 1:100,000 to 10:1.

212. (New) A composition according to Claim 211 in the form of a compressible powder or of compressible granules.

213. (New) A composition according to Claim 211 including a rate-controlling polymeric material.

214. (New) A composition according to Claim 212 including a rate-controlling polymeric material.

215. (New) A composition according to Claim 211 including auxiliary recipients selected from the group consisting of diluents, lubricants, disintegrants, plasticizers, anti-tack agents, opacifying agents, pigments, and flavorings, and a mixture of two or more of the foregoing.

216. (New) A composition according to Claim 215 including a diluent which is an inert filler selected from the group consisting of microcrystalline cellulose, lactose, diabasic calcium phosphate, saccharides, and mixtures of any of the foregoing.

217. (New) A composition according to Claim 216 including microcrystalline cellulose as an inert filler.

218. (New) A composition according to Claim 216 including a lactose selected from the group consisting of lactose monohydrate and lactose anhydrous.

219. (New) A composition according to Claim 216 including a saccharide selected from the group consisting of mannitol, starch, sorbitol, sucrose, and glucose.

220. (New) A composition according to Claim 215 including a lubricant selected from the group consisting of colloidal silicon dioxide, talc, and stearic acid.

221. (New) A composition according to Claim 215 including a disintegrant selected from the group consisting of lightly crosslinked polyvinylpyrrolidone, corn starch, potato starch, maize starch and modified starches, croscarmellose sodium, crosspovidone, and sodium starch glycolate.

222. (New) A composition according to claim 211 which includes:

(A) a drug selected from the group consisting of peptides, proteins, oligosaccharides polysaccharides, and hormones; and

(B) an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

223. (New) A composition according to claim 211 which includes an anticoagulant drug and an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

224. (New) A composition according to claim 223 wherein the anticoagulant drug is selected from the group consisting of heparin, low molecular weight heparin, heparanoid, hirudin, and analogues thereof.

225. (New) A composition according to claim 224 including heparin.

226. (New) A composition according to claim 224 including low molecular weight heparin.

227. (New) A composition according to claim 225 wherein the enhancer is sodium caprate and the ratio of the heparin to the sodium caprate is 1:1000 to 10:1.

228. (New) A composition according to claim 226 wherein the enhancer is sodium caprate and the ratio of the low molecular weight heparin to the sodium caprate is 1:1000 to 10:1.

229. (New) A composition according to claim 211 including a bisphosphonate and an enhancer selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

230. (New) A composition according to claim 229 wherein the bisphosphonate is alendronate.

231. (New) A composition according to claim 229 wherein the bisphosphonate is etidronate.

232. (New) A composition according to claim 230 wherein the enhancer is sodium caprate and the ratio of alendronate to sodium caprate is 1:1000 to 10:1.

233. (New) A composition according to claim 222 including a peptide drug.

234. (New) A composition according to claim 222 including a protein drug.

235. (New) A composition according to claim 222 including an oligosaccharide drug.

236. (New) A composition according to claim 222 including a polysaccharide drug.

237. (New) A composition according to claim 222 including a hormone drug.

238. (New) A composition according to claim 211 wherein the enhancer is sodium caprate.

239. (New) A composition according to claim 211 wherein the enhancer is a combination of medium chain fatty acid salts having a carbon chain length of from 8 to 14 carbon atoms and the combination is the only enhancer present in the composition.

240. (New) A solid oral dosage form which is effective in delivering a drug and an enhancer, each as defined below, to an intestine and which comprises an enterically coated pharmaceutical composition consisting essentially of:

(A) about 0.5 μg to about 1000 mg of a drug which: (1) is present in a therapeutically effective amount; (ii) is crystalline or amorphous; and (iii) is selected from the group consisting peptides, proteins, oligosaccharides, polysaccharides, hormones, bisphosphonates, and anti-coagulants; and

(B) sodium caprate which: (i) is the only enhancer present in the composition; and (ii) is present in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:1,000 to 10:1 and such that the enhancer enhances intestinal delivery of the drug to the underlying circulation.

241. (New) A form according to claim 240 wherein the drug is a peptide.

242. (New) A form according to claim 240 wherein the drug is a bisphosphonate.

243. (New) A form according to claim 240 wherein the drug is alendronate.

244. (New) A form according to claim 240 wherein the drug is an anti-coagulant.

245. (New) A form according to claim 240 wherein the drug is low molecular weight heparin.

246. (New) A compressible composition which is capable of being compressed into a solid oral pharmaceutical dosage form which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to an intestine, said composition consisting essentially of:

(A) a drug which: (i) is crystalline or amorphous; and (ii) is selected from the group consisting peptides, proteins, oligosaccharides, polysaccharides, hormones, bisphosphonates, and anti-coagulants; and

(B) sodium caprate which: (i) is the only enhancer present in the composition; and (ii) is present in an amount and such that the ratio of the drug to the sodium caprate is 1:1,000 to 10:1.

247. (New) The composition of claim 246, wherein the drug is a peptide.

248. (New) The composition of claim 246, wherein the drug is a bisphosphonate.

249. (New) The composition of claim 246, wherein the bisphosphonate is alendronate.

250. (New) The composition of claim 246, wherein the drug is an anti-coagulant.

251. (New) The composition of claim 246, wherein the drug is low molecular weight heparin.

252. (New) A process for the manufacture of a composition which is capable of being compressed into a solid oral dosage form which is effective in delivering therapeutically

effective amounts of a drug and an enhancer, as defined below, to the intestine, the process comprising the steps of:

(A) providing compressible constituents consisting essentially of:

(1) a drug which: (i) is present in a therapeutically effective amount; (ii) is crystalline or amorphous; and (iii) is hydrophilic or macromolecular; and

2) an enhancer which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon chain length of from 8 to 14 carbon atoms and is the only enhancer present in the composition; (iii) is present in a therapeutically effective amount and such that the ratio of the drug to the enhancer is 1:100,000 to 10:1 and such that the enhancer enhances intestinal delivery of the drug to the underlying circulation; and

(B) combining the constituent to form a compressible powder or compressible granules.

253. (New) A form according to Claim 178 wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.

254. (New) A composition according to Claim 211 wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.

255. (New) A form according to Claim 240 wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.

256. (New) A composition according to Claim 246 wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.

257. (New) A process according to Claim 252 wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.